

## **REMARKS**

The Office Action dated November 19, 2004 has been carefully considered. Claims 1 and 50-69 are pending in the present application. Claim 1 has been amended to more particularly point out and distinctly claim the present invention. The amendments to claim 1 and new claims 70-89 are fully supported by the originally-filed specification at, for example, page 6, lines 28-29, Figure 11, and original claims 1-49. No new matter has been added. Reconsideration of the present application and entry of the above amendments in view of the following remarks are respectfully requested.

### **I. RESTRICTION REQUIREMENT**

In the Office Action dated November 19, 2004, the Examiner alleges that: "Newly submitted claims 50-69 are directed to an invention that lacks unity with the invention originally claimed for the following reasons: Applicant's original claim 1 was directed towards an article in class 623/1. subclass 1.46 and new claims are directed towards methods of manufacture a stent coating class 427 subclass 2.24." The Examiner further stated that "since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 50-69 are withdrawn from consideration."

Applicants respectfully traverse the restriction requirement and assert that even assuming, *arguendo*, that original claim 1 and claims 50-69 represent distinct or independent inventions, to search and examine the subject matter of all the claims together would not be a serious burden on the Examiner. It is noted that M.P.E.P. § 811(Eighth Edition August 2001, Latest Revision May 2004) states that: "Before making a restriction requirement after the first action on the merits, the examiner will consider whether there will be a serious burden if restriction is not required." In addition, M.P.E.P. § 803 states that: "If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions."

Applicants respectfully assert that the subject matter of originally-presented claim 1 and claims 50-69 are so intertwined that a single search would identify any relevant art pertaining to a stent and a method of making such stent. Thus, in view of M.P.E.P. §§ 803 and 811, it is respectfully submitted that the subject matter of original claim 1 and claims 50-69 should be searched and examined in the subject application as it would not be a serious

burden. Accordingly, Applicants respectfully request that the restriction requirement be withdrawn or modified such that the subject matter of claims 1 and 50-69 are examined in one application.

In order to be fully responsive, however, Applicants hereby elect to prosecute claim 1, with traverse, without prejudice to Applicants' rights to pursue the non-elected subject matter in other applications. New claims 70-89 depend from claim 1 and are directed to methods of manufacturing the stent of claim 1.

## **II. CLAIM REJECTION UNDER 35 U.S.C. § 102(e)**

Claim 1 is rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 6,488,701 to Nolting *et al.* ("Nolting"). This rejection is respectfully traversed. It is believed that claim 1 and new claims 70-89 depending therefrom are patentable over Nolting for the following reasons.

Claim 1, as amended herein, recites "An expandable intraluminal stent comprising a main body portion having a first end portion, a second end portion, a middle portion and a flow passage defined therethrough, at least a portion of the first end portion having a biocompatible coating directly thereon, wherein the biocompatible coating comprises a polymer or a drug, and wherein the middle portion surface is free of the biocompatible coating."

New claims 70-86 are directed to a method of manufacturing the stent of claim 1 comprising providing a main body portion having a first end portion, a second end portion, and a middle portion having a surface and a flow passage defined therethrough, wherein the first end portion comprises an edge, and forming a biocompatible coating directly on at least a portion of the edge, wherein the middle portion surface is free of the biocompatible coating.

New claims 87 and 88 are directed to a method for manufacturing the stent of claim 1 comprising providing a main body portion having a first end portion, a second end portion, a middle portion having an outer surface and a flow passage defined therethrough, wherein the first end portion comprises a first edge and the second end portion comprises a second edge, forming a first biocompatible coating directly on at least a portion of the first edge, and forming a second biocompatible coating directly on at least a portion of the second edge, wherein the first biocompatible coating and the second biocompatible coating each comprise a polymer or a drug and the middle portion surface is free of the first or second biocompatible coating.

New claim 89 recites a method for manufacturing the stent of claim 1 comprising providing a main body portion having a first end portion, a second end portion, a middle

portion having an outer surface, and a flow passage defined therethrough, wherein the first end portion comprises an edge and applying a sleeve directly on at least a portion of the edge, wherein the sleeve comprises at least one layer of a material comprising a bioadhesive, a drug, or a combination thereof, and wherein the middle portion surface is free of the layer of material.

Nolting discloses a stent-graft assembly comprising a stent having at least one support member wherein “[s]ome or all of the support member or members comprise a coating which substantially encapsulates the coated support member or members” and “the stent-graft includes an ultra-thin membrane or covering which is attached to the coating.” (Col. 5, lines 32-38). To make Nolting’s stent-graft assembly, a coating is applied to a stent, and then the coated stent is covered or lined with a thin tube or membrane. (Col. 6, lines 4-6). Nolting further discloses that a solvent is introduced to attach the coating to the membrane and then the stent-graft assembly is cured. (Col. 6, lines 6-8).

However, unlike in the present invention, Nolting does not disclose or suggest that the surface of the middle portion of its stent is free of the coating which directly covers or contacts the surface of the end portion or an edge of the end portion. In fact, Nolting teaches that the coating **20** that is directly disposed on the surface of the ends of its stent also covers the surface of the middle of Nolting’s stent (*see* Figure 2 of Nolting). Thus, by teaching that the coating **20**, which is applied directly to the surface of the ends of the stent, covers the surface of the middle of Nolting’s stent, Nolting teaches away from the present invention where the surface of the middle portion of the stent is free of the coating that is applied directly to the end portions of the stent.

Furthermore, Nolting also fails to teach or disclose a sleeve that is in direct contact with at least a portion of the edge, wherein the middle portion surface of the stent is free of the sleeve material, as recited in claim 89.

For the above reasons, it is believed that claims 1 and 70-89 are patentable over Nolting. Accordingly, allowance of claims 1 and 70-89 is respectfully requested.

### III. CONCLUSION

In light of the above amendments and remarks, it is believed that the rejections have been overcome and that the present application is in condition for allowance. Should the Examiner not agree with Applicants' position, then a personal or telephonic interview is respectfully requested to discuss any remaining issues and expedite the eventual allowance of the application.

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Respectfully submitted,

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Enclosures